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ORIGINAL RESEARCH

Development and Psychometric Validation of the ASMA Medication Adherence Questionnaire for Adults with Type 2 Diabetes in Saudi Arabia: A Cross-Sectional Study

Nouf Aloudah

Department of Clinical Pharmacy, College of Pharmacy, King Saud University, Riyadh, Saudi Arabia

Correspondence: Nouf Aloudah, Department of Clinical Pharmacy, College of Pharmacy, King Saud University, P.O. Box 11523, Riyadh, 13213-6921, Saudi Arabia, Email naloudah@ksu.edu.sa

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Background and Purpose: Medication adherence remains a major challenge in the management of type 2 diabetes, contributing to poor glycaemic control, preventable complications, and increased healthcare burden despite advances in treatment. Existing adherence measures often quantify medication-taking behaviour but provide limited insight into the behavioural, psychological, and contextual determinants that influence long-term adherence. The aim of this study was to develop and psychometrically evaluate a theory-informed, patient-derived questionnaire (ASMA) to assess medication adherence and its behavioural determinants among adults with type 2 diabetes mellitus.

Methods: His cross-sectional instrument development and validation study was conducted at a tertiary diabetes care centre in Riyadh, Saudi Arabia. Adults aged ≥18 years who had been receiving oral hypoglycaemic therapy for at least 12 months were recruited. Questionnaire items were derived from prior qualitative patient interviews and mapped to the Theoretical Domains Framework (TDF). Medication adherence outcomes were descriptively assessed using three self-reported items aligned with the ABC taxonomy of medication adherence, capturing initiation, implementation, and persistence of medication-taking behaviour.

Results: A total of 145 participants were included (59.3% female), with a median diabetes duration of 10.5 years (IQR 6.0–20.0). Most participants reported adherence across ABC phases: 91.8% reported always taking medication as prescribed (implementation), 97.9% reported initiation of therapy, and 84.2% reported persistent medication use. Sampling adequacy was acceptable (KMO=0.74), and Bartlett's test was significant ($\chi^2(325)=1214$, $p<0.001$). Exploratory factor analysis supported a four-factor structure after item refinement. The retained domains were: Psychological and Behavioral Regulation (9 items), Perceived Control and Treatment Facilitation (5 items), Knowledge and Informational Support (3 items), and Beliefs about Consequences (2 items). Factor loadings ranged from 0.69 to 0.82 within the unidimensional four-item domain. The four-factor solution demonstrated conceptual coherence and adequate variance explanation. Internal consistency was good for the Psychological and Behavioral Regulation domain ($\alpha=0.81$; $\omega=0.83$), while other domains showed moderate reliability, likely reflecting fewer items.

Conclusion: The ASMA questionnaire demonstrates preliminary evidence of structural validity and reliability as a multidimensional, theory-informed instrument. It may support the identification of modifiable behavioural determinants of medication adherence and inform targeted, patient-centred interventions in adults with type 2 diabetes. Further confirmatory validation is warranted.

Keywords: medication adherence, type 2 diabetes mellitus, questionnaire development, psychometrics, patient-reported outcomes

Introduction

Medication adherence remains a central challenge in the management of type 2 diabetes and represents a major public health and health-system concern worldwide. Despite substantial advances in pharmacological therapies, a significant proportion of adults with type 2 diabetes do not take their medications as prescribed, contributing to suboptimal glycaemic control, preventable complications, increased healthcare utilisation, and widening health inequities.

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Furthermore, non-adherence undermines the effectiveness of evidence-based treatments and places a sustained burden on healthcare systems, particularly in settings where long-term disease management relies heavily on patient self-care. These challenges persist across diverse healthcare contexts, indicating that medication adherence in diabetes is not solely a function of drug availability or clinical efficacy, but is shaped by broader behavioural and contextual factors.[1]

Although medication adherence is widely recognised as a multidimensional behaviour, its assessment in both research and routine clinical practice has often relied on tools that primarily quantify medication-taking behaviour, such as missed doses or prescription refills. While such measures provide useful estimates of adherence levels, they offer limited insight into the behavioural, psychological, and contextual determinants that influence why patients adhere or fail to adhere over time. As a result, these tools are often poorly suited to informing the design of targeted interventions or to guiding clinician–patient conversations about adherence in real-world care. This limitation is particularly salient in chronic conditions such as type 2 diabetes, where treatment regimens are long-term, self-managed, and embedded within daily routines and social environments.[2,3]

In contrast, approaches grounded in qualitative and patient-centred research have consistently demonstrated the value of capturing patients' lived experiences of medication use. Qualitative studies have shown that adherence is influenced by a complex interplay of knowledge, beliefs about treatment and illness, emotional responses, prior experiences, social relationships, and practical constraints. Questionnaires derived from such work are better positioned to reflect how patients experience long-term pharmacotherapy in everyday life, rather than reducing adherence to a single behavioural outcome. Importantly, patient-derived tools can identify determinants that are clinically meaningful and potentially modifiable, thereby bridging the gap between measurement and action. This is particularly relevant for type 2 diabetes, where adherence behaviour evolves over time and is shaped by changing life circumstances, treatment demands, and health perceptions.[4,5]

Additionally, medication adherence can be conceptualized within the ABC taxonomy, which describes adherence as a process comprising initiation, implementation, and discontinuation of medication-taking behaviour, thereby providing a standardized framework for adherence research.[6] Despite this conceptual clarity, many commonly used instruments primarily assess the level of adherence behaviour, such as how consistently patients take their medications. While these measures offer useful estimates of adherence, they provide limited insight into the underlying behavioural, cognitive, and contextual determinants that influence medication-taking. Consequently, identifying the drivers of adherence often requires additional qualitative or theory-informed investigation. This underscores the need for instruments that integrate the measurement of adherence behaviour with the assessment of its determinants within a single structured tool.[7]

Understanding adherence determinants is not an end in itself, but a necessary step toward improving medication use in practice. There is increasing recognition that "one-size-fits-all" adherence interventions are unlikely to be effective across heterogeneous patient populations. Instead, interventions that are tailored to specific behavioural and contextual domains—such as patients' perceived control over treatment, their understanding of the condition, emotional responses to medication, or beliefs about consequences—are more likely to address the underlying drivers of non-adherence. Mapping adherence-related domains to potential intervention targets offers a pragmatic framework for translating patient-reported data into actionable strategies for clinicians, health systems, and policymakers. Such an approach aligns with broader movements toward person-centred and integrated care, which emphasise responsiveness to individual needs while addressing population-level challenges.[8]

In addition, behavioural determinants of adherence are increasingly examined using theory-informed frameworks such as the Theoretical Domains Framework (TDF), which integrates multiple behaviour change theories to systematically identify psychological, social, and environmental factors influencing health behaviours.[8]

Within this context, there remains a need for theory-informed, patient-derived questionnaires that can systematically assess the behavioural and contextual dimensions of medication adherence in adults with type 2 diabetes. Tools that combine conceptual grounding with empirical validation have the potential to support both research and clinical practice by identifying key domains that shape adherence and by informing the design of targeted interventions. However, few existing questionnaires have been explicitly developed from qualitative patient data while also demonstrating psychometric robustness and practical relevance. The present study was therefore undertaken to address this gap. The first objective was to develop and psychometrically validate a theory-informed questionnaire assessing medication adherence

among patients with type 2 diabetes, drawing on qualitative insights into patients' experiences of long-term medication use. The second objective was to examine the questionnaire's capacity to map adherence-related domains to potential intervention targets anticipated to improve medication adherence. By focusing on both measurement and applicability, this study aims to contribute evidence that supports a more nuanced, behaviourally informed approach to understanding and addressing medication adherence in type 2 diabetes at both individual and population levels.

Methods

Study Design

A cross-sectional, theory-based questionnaire development study was conducted to develop and perform an initial psychometric evaluation of a self-reported medication adherence questionnaire for patients with type 2 diabetes.

Questionnaire

Tool Development

The study questionnaire was a theory-based, self-reported questionnaire developed to assess medication adherence and its determinants among patients with type 2 diabetes. The questionnaire was informed by a prior qualitative study that used theory-informed, in-depth interviews with patients diagnosed with type 2 diabetes to explore factors influencing medication-taking behavior.[7] Qualitative data were analyzed using the Theoretical Domains Framework (TDF), a comprehensive framework integrating multiple behavioral theories relevant to health behavior change.[9] The use of TDF ensured that item development systematically covered cognitive, emotional, social, and environmental determinants of adherence. The qualitative analysis identified 38 distinct factors perceived by patients to influence adherence behavior. Conceptually overlapping factors were combined, and items were refined to ensure clarity and avoid redundancy, resulting in a 29-item determinant scale. These factors were translated into 29 questionnaire items assessing determinants of medication-taking behavior, in addition to three items assessing medication adherence outcomes. Items were worded to reflect both positively and negatively framed statements to minimize acquiescence and response bias. All determinant items were measured using a five-point Likert scale, ranging from strong disagreement to strong agreement. Content validity was assessed through expert review by three professionals with expertise in medication adherence and diabetes care. Experts evaluated item relevance, clarity, and comprehensiveness. Minor wording refinements were made based on their feedback.

Piloting

The questionnaire was developed in Arabic, with item wording and ordering reviewed by two researchers with expertise in medication adherence and health services research. The draft questionnaire was piloted with 10 patients with type 2 diabetes to assess clarity, relevance, and comprehensibility, leading to minor refinements prior to field administration. Feedback from pilot participants informed minor wording refinements without altering the conceptual structure of the instrument. An English translation of the questionnaire is provided for reporting purposes.

Setting, Participants and Patient's Recruitment

This cross-sectional study was conducted between January 2023 and January 2024 in a sample of participants recruited from the Diabetes Medical Center of King Khalid University Hospital (KKUH), an academic tertiary care hospital affiliated with King Saud University in Riyadh, Saudi Arabia. The center provides specialised outpatient care for adults with diabetes, including long-term pharmacological management and structured follow-up, and serves a diverse patient population drawn from routine clinical practice. Time frame-Patient recruitment was conducted during routine clinic visits. While patients were waiting for their scheduled appointments, a trained diabetes educator or nurse initially screened potential participants by reviewing their medical records against the predefined eligibility criteria. Eligible patients were then invited to participate and referred to the researcher.

The researcher subsequently re-confirmed eligibility, provided a detailed explanation of the study objectives and procedures, and shared the participant information sheet. Written informed consent was obtained from all participants

prior to enrollment. Patients who requested additional time to consider participation or wished to consult family members were provided with contact details, and a follow-up meeting with the researcher was arranged within seven days.

After consent was obtained, the questionnaire was administered electronically using Google Forms. A secure survey link was sent to each participant's personal mobile phone via WhatsApp, allowing participants to complete the questionnaire at their convenience. This approach enabled private, self-administered completion of the questionnaire, with the researcher available to respond to questions or provide clarification if needed.

Eligible participants were adults aged 18 years or older with a confirmed diagnosis of type 2 diabetes for at least 12 months, who had received at least two prescriptions for oral hypoglycemic medications in the 12 months preceding the index date, and had a documented HbA1c measurement within one year of that date. Patients were excluded if they had a diagnosis of gestational diabetes, were using insulin or managing diabetes through diet alone without oral hypoglycemic medications or had a hearing impairment that could affect informed participation.

Patient and Public Involvement

Patients were involved in the initial qualitative phase of the study through in-depth interviews that informed item generation and content development of the questionnaire. Patients were not involved in the study design, data analysis, or interpretation of results. The findings will be disseminated through academic publications and presentations. The study is reported in accordance with the CHERRIES guideline for reporting results of internet-based surveys.

Data Collection and Study Outcomes

Data was collected using a structured, self-administered questionnaire delivered electronically. The questionnaire comprised two main sections. The first section collected demographic and clinical characteristics reflecting the participants' status. This included age (years), sex (male/female), body mass index (BMI; calculated as weight in kilograms divided by height in meters squared), educational level (no formal education, high school or below, college or higher), marital status (single, married, divorced, widowed), and monthly household income. Income was categorized as follows: ≤5,000 Saudi Riyals (SAR; ≈1,330 USD), 5,000–10,000 SAR (≈1,330–2,660 USD), >10,000–20,000 SAR (≈2,660–-5,330 USD), >20,000–35,000 SAR (≈5,330–9,330 USD), and >35,000 SAR (≈9,330+ USD). Clinical variables included duration of diabetes (years) and duration of diabetes medication use (years).

The second section assessed medication adherence and factors influencing medication-taking behavior. Medication adherence was measured using three self-reported items aligned with the ABC taxonomy of medication adherence, capturing initiation, implementation, and persistence. Determinants of medication-taking behavior were assessed using multiple items derived from theory-informed qualitative interviews and mapped to behavioral domains.

Sample Size, Data Analysis and Data Handling

The sample size was determined based on established recommendations for questionnaire development and exploratory factor analysis. Given that the questionnaire comprised 29 items, and applying a commonly cited subject-to-item ratio of approximately 4:1, a minimum sample size of 116 participants was considered sufficient for initial exploratory psychometric evaluation of the questionnaire. Although recommendations for factor analysis sample size vary, such ratios are widely used in early-stage questionnaire development to support assessment of internal structure.[10]

Exploratory factor analysis was conducted using Jamovi (version 2.6.44, solid release),[11] an open-source statistical platform built on R software, which provides access to a comprehensive range of advanced EFA techniques while offering a user-friendly graphical interface that facilitates transparent and reproducible analyses in applied health research which enabled implementation of contemporary psychometric and descriptive analytic approaches suitable for questionnaire development.[12] Descriptive statistics were calculated to summarize participant characteristics, adherence outcomes, and item-level responses. Internal consistency was assessed using Cronbach's alpha coefficient, with estimates calculated at the factor level following identification of the underlying factor structure.

Structural validity was evaluated using exploratory factor analysis (EFA). Prior to factor extraction, the suitability of the data for factor analysis was assessed using the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity. Common-factor extraction methods and oblique rotation were applied to allow for correlated

latent constructs. Factor retention was guided by eigenvalues, scree plot inspection, and parallel analysis, alongside interpretability of the factor solution. Data handling procedures included checking for missing values and ensuring appropriate coding of questionnaire responses prior to analysis. Analyses were conducted using complete cases for psychometric evaluation.

Item-level descriptive statistics were calculated for items 4–29, which assess determinants of medication-taking behavior. As these items were measured using a five-point Likert scale, they were treated as ordinal variables for descriptive analyses. For each item, measures of central tendency and dispersion were computed, including the mean, standard deviation, median, interquartile range (IQR), and observed minimum and maximum values. Missing responses were reported at the item level. Floor and ceiling effects were examined using response distributions. A floor effect was considered present if more than 15% of respondents selected the lowest response option, while a ceiling effect was considered present if more than 15% selected the highest response option. Floor and ceiling effects were assessed descriptively for each item and reported separately from other descriptive statistics. Furthermore, exploratory factor analysis was conducted on items 4–29, which assess determinants of medication-taking behavior. Factors were extracted using an appropriate extraction method for ordinal data, and an oblique rotation was applied to allow for correlations between factors. The initial number of factors was guided by eigenvalues, scree plot inspection, and interpretability of the factor solution. An initial five-factor solution was explored based on empirical criteria and theoretical considerations. To examine the robustness and parsimony of the factor structure, alternative models were subsequently evaluated. Five, four-factor and three-factor solutions were extracted and compared to the initial solution based on factor loadings, cross-loadings, item distribution across factors, and conceptual coherence of the resulting domains. The study is reported in accordance with the STROBE guideline for cross-sectional studies and a completed STROBE checklist is provided as supplementary material.

Ethics Approval and Consent to Participate

Ethical approval for the study was obtained from the Institutional Review Board (IRB) of King Saud University, Riyadh, Saudi Arabia (IRB approval number E-20-4829). The study was reviewed under an expedited review process and approved on 17 November 2020. The qualitative study that informed questionnaire development was conducted as a separate study and received ethical approval from the Institutional Review Board (IRB) of the Medical College of King Saud University (E-13-1058) where the participants were recruited, and the College Ethical Review Board (CERB), University of Aberdeen (CERB/2014/1/975).[7] All procedures were conducted in accordance with institutional research policies and the principles of the Declaration of Helsinki. Participation was voluntary, and informed consent was obtained from all participants prior to data collection. The study involved no disclosure of participant identity and posed no more than minimal risk to participants.

Results

Participant Characteristics

A total of 145 participants were included, 59.3% of whom were female (n=86). Most participants were married (80.8%, n=118), with smaller proportions who were single (7.5%, n=11), divorced (4.8%, n=7), or widowed (6.8%, n=10). Monthly income varied, with 32.9% (n=48) reporting 5,000–10,000 SAR (USD 1,333–2,667), 30.1% (n=44) reporting 10,000–20,000 SAR (USD 2,667–5,333), and 24.0% (n=35) reporting <5,000 SAR (<USD 1,333); fewer participants reported incomes of 20,000–35,000 SAR (USD 5,333–9,333) (6.2%, n=9) or >35,000 SAR (>USD 9,333) (6.8%, n=10).

Educational attainment varied, with 41.1% (n=60) having completed college education or higher, 32.2% (n=47) having secondary education, and 26.7% (n=39) having elementary education. The median duration of diabetes was 10.5 years (IQR 6.0–20.0; range 1–35), and the median duration of diabetes medication use was 10.0 years (IQR 5.25–20.0; range 1–35). Participant characteristics are summarised in Table 1.

Table 1 Participant Demographic and Clinical Characteristics

Characteristic	Category/Statistic	n	%/Value
Sex	Female	86	59.3
	Male	59	40.7
Marital status	Married	118	80.8
	Single	11	7.5
	Divorced	7	4.8
	Widowed	10	6.8
Education level	Elementary	39	26.7
	Secondary	47	32.2
	College or higher	60	41.1
Monthly income (SAR)	< 5,000 (< USD 1,333)	35	24.0
	5,000–10,000 (USD 1,333–2,667)	48	32.9
	10,000–20,000 (USD 2,667–5,333)	44	30.1
	20,000–35,000 (USD 5,333–9,333)	9	6.2
	> 35,000 (> USD 9,333)	10	6.8
Duration of diabetes (years)	Median (IQR)	10.5 (6.0–20.0)	
	Range	1–35	
Duration of diabetes medication use (years)	Median (IQR)	10.0 (5.25–20.0)	
	Range	1–35	

Notes: Values are presented as number (percentage) unless otherwise indicated. Clinical variables are reported as median (interquartile range). One response was missing for sex. USD equivalents are approximate based on an exchange rate of 1 USD ≈ 3.75 SAR.

Medication Adherence Outcomes

Medication adherence outcomes were assessed descriptively using three self-reported questions aligned with the ABC taxonomy of medication adherence[6] (Table 2). Implementation was evaluated using Q1, which assessed overall medication-taking behavior as prescribed. Most participants reported always taking their medication as prescribed (n = 134, 91.8%), while a smaller proportion reported sometimes adhering to the prescribed regimen (n = 12, 8.2%); no

Table 2 Medication Adherence Outcomes

Adherence Measure	Response Category	n	%
Overall adherence (Q1)	Always	134	91.8
	Sometimes	12	8.2
	Never	0	0
Initiation (Q2)	Yes	140	97.9
	No	3	2.1

(*Continued*)

Table 2 (Continued).

Adherence Measure	Response Category	n	%
Persistence (Q3)	Always	123	84.2
	Sometimes	17	11.6
	Never	6	4.1

Notes: Values are presented as number (percentage). Responses labelled as "cannot remember" were excluded from the analysis where applicable.

participants reported never adhering. Initiation was assessed using Q2, which captured whether participants took the first prescribed dose of their diabetes medication. Nearly all participants reported initiation of therapy (n = 140, 97.9%), whereas a small minority reported not taking the first dose (n = 3, 2.1%). Persistence was evaluated using Q3, reflecting continued adherence to the prescribed dosing regimen over time. The majority of participants reported always maintaining the prescribed dosing from initiation to the most recent dose (n = 123, 84.2%), while some reported sometimes doing so (n = 17, 11.6%) or never maintaining persistence (n = 6, 4.1%).

Item Descriptive Statistics

Exploratory factor analysis was conducted using jamovi, as it facilitates the implementation of contemporary psychometric best practices relevant to questionnaire development in health services research. Specifically, jamovi allows transparent specification of common-factor extraction methods, oblique rotations for correlated constructs, and parallel analysis for factor retention, which is recommended over traditional eigenvalue-based criteria. Descriptive statistics for items 4–29 are presented in Table 3. Across items, mean scores generally fell within the mid-to-upper range of the response scale, with variability observed in standard deviations and interquartile ranges, indicating heterogeneity in

Table 3 Descriptive Statistics for Items Q4–Q29

Item	N	Mean	SD	Median	Q1	Q3	Min	Max
4	146	2.73	1.65	3.00	1.00	4.00	1	5
5	146	3.32	1.69	4.00	1.00	5.00	1	5
6	146	4.27	0.99	5.00	4.00	5.00	1	5
7	146	4.36	0.94	5.00	4.00	5.00	1	5
8	146	3.57	1.39	4.00	2.25	5.00	1	5
9	146	3.69	1.39	4.00	3.00	5.00	1	5
10	146	4.67	0.69	5.00	5.00	5.00	1	5
11	146	4.41	0.91	5.00	4.00	5.00	1	5
12	146	4.20	0.84	4.00	4.00	5.00	1	5
13	146	3.56	1.42	4.00	2.00	5.00	1	5
14	146	3.90	1.14	4.00	3.00	5.00	1	5
15	146	3.74	1.44	4.00	2.25	5.00	1	5
16	146	4.38	0.68	4.00	4.00	5.00	2	5
17	146	1.72	1.23	1.00	1.00	2.00	1	5

(*Continued*)

Table 3 (Continued).

Item	N	Mean	SD	Median	Q1	Q3	Min	Max
18	146	1.99	1.39	1.00	1.00	2.00	1	5
19	146	2.65	1.60	2.00	1.00	4.00	1	5
20	146	3.86	1.40	4.00	4.00	5.00	1	5
21	146	2.01	1.38	1.00	1.00	2.75	1	5
22	146	3.65	1.41	4.00	3.00	5.00	1	5
23	146	3.29	1.66	4.00	2.00	5.00	1	5
24	146	4.64	0.52	5.00	4.00	5.00	3	5
25	146	4.47	0.77	5.00	4.00	5.00	1	5
26	146	4.50	0.81	5.00	4.00	5.00	1	5
27	146	2.39	1.46	2.00	1.00	4.00	1	5
28	146	2.71	1.54	2.00	1.00	4.00	1	5
29	146	4.53	0.72	5.00	4.00	5.00	2	5

participants' responses. All items demonstrated the full range of possible responses, with observed minimum and maximum values corresponding to the lowest and highest response options. Item-level analysis of response distributions identified the presence of floor and/or ceiling effects for several items, as more than 15% of respondents selected the lowest or highest response category, respectively (Table 4). Other items showed a more even distribution across response options, with no substantial floor or ceiling effects observed. These findings reflect variation in the distributional properties of individual items and are reported descriptively, without aggregation or weighting.

Table 4 Floor and Ceiling Effects for ASMA Items (Q4–Q29)

Item	N	Floor n (%)	Ceiling n (%)	Floor Effect >15%	Ceiling Effect >15%
4	146	58 (39.7%)	35 (24.0%)	Yes	Yes
5	146	43 (29.5%)	54 (37.0%)	Yes	Yes
6	146	5 (3.4%)	79 (54.1%)	No	Yes
7	146	3 (2.1%)	83 (56.8%)	No	Yes
8	146	19 (13.0%)	48 (32.9%)	No	Yes
9	146	18 (12.3%)	54 (37.0%)	No	Yes
10	146	1 (0.7%)	110 (75.3%)	No	Yes
11	146	3 (2.1%)	86 (58.9%)	No	Yes
12	146	1 (0.7%)	62 (42.5%)	No	Yes
13	146	23 (15.8%)	45 (30.8%)	Yes	Yes
14	146	5 (3.4%)	54 (37.0%)	No	Yes
15	146	20 (13.7%)	59 (40.4%)	No	Yes

(*Continued*)

Table 4 (Continued).

Item	N	Floor n (%)	Ceiling n (%)	Floor Effect >15%	Ceiling Effect >15%
16	146	0 (0.0%)	69 (47.3%)	No	Yes
17	146	97 (66.4%)	9 (6.2%)	Yes	No
18	146	81 (55.5%)	13 (8.9%)	Yes	No
19	146	56 (38.4%)	29 (19.9%)	Yes	Yes
20	146	20 (13.7%)	64 (43.8%)	No	Yes
21	146	81 (55.5%)	11 (7.5%)	Yes	No
22	146	19 (13.0%)	54 (37.0%)	No	Yes
23	146	36 (24.7%)	56 (38.4%)	Yes	Yes
24	146	0 (0.0%)	97 (66.4%)	No	Yes
25	146	1 (0.7%)	86 (58.9%)	No	Yes
26	146	3 (2.1%)	90 (61.6%)	No	Yes
27	146	57 (39.0%)	17 (11.6%)	Yes	No
28	146	48 (32.9%)	25 (17.1%)	Yes	Yes
29	146	0 (0.0%)	92 (63.0%)	No	Yes

Notes: Floor and ceiling effects were assessed according to COSMIN recommendations. An effect was considered present if more than 15% of respondents selected the lowest or highest response option.

Structural Validity

The suitability of the data for factor analysis was examined prior to factor extraction. Sampling adequacy was supported by a Kaiser–Meyer–Olkin (KMO) measure of 0.74, indicating an acceptable level of shared variance among items. Bartlett's test of sphericity was statistically significant ($\chi^2(325) = 1214$, $p < 0.001$), confirming that the correlation matrix was appropriate for factor analysis. Exploratory factor analysis (EFA) was conducted using the minimum residual extraction method with oblimin rotation to allow for correlated factors. Parallel analysis initially suggested a five-factor solution. However, examination of factor loadings in the five-factor model revealed limited interpretability, with several items exhibiting low primary loadings (<0.40) or substantial cross-loadings across multiple factors. Subsequent inspection of alternative solutions indicated that a four-factor structure provided a more coherent and parsimonious representation of the data. The four-factor solution demonstrated clearer item clustering, reduced cross-loadings, and improved interpretability compared with the five-factor model, while retaining adequate variance explanation. A three-factor solution was also explored using the same extraction and rotation methods. Compared with the four-factor model, the three-factor solution showed greater factor complexity, increased cross-loadings, and reduced conceptual distinction between domains. Based on comparative evaluation of factor interpretability, loading patterns, and dimensional clarity, the four-factor solution was retained as the most appropriate representation of the underlying structure of the questionnaire. Exploratory factor analysis supported a unidimensional structure for the four-item domain, with all items loading strongly on a single factor (loadings 0.69–0.82) and explaining 58% of the variance, meeting COSMIN criteria for sufficient structural validity. The exploratory factor analysis results for the ASMA questionnaire domains and items are presented in Table 5.

During the initial exploratory factor analysis, item Q15 demonstrated weak factor loadings and/or substantial cross-loadings across multiple factors. These items were therefore removed in the early stages of model refinement to improve the clarity and stability of the factor structure. In subsequent analyses, items Q6 and Q22 failed to load meaningfully on any factor and exhibited high uniqueness. As a result, these items were also excluded from the final factor solution.

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Table 5 Exploratory Factor Analysis Results for ASMA Questionnaire Domains and Items

		Item	Factor 1	Factor 2	Factor 3	Factor 4	Uniqueness
Psychological and Behavioral Adaptation to Diabetes Medication	Q17	Have you ever decided not to take your medication when experiencing psychological or social stress?	0.77				0.428
	Q21	Do social pressures affect your taking of diabetes medications?	0.743				0.443
	Q28	Does taking diabetes medication make you feel bored or fatigued?	0.66				0.579
	Q27	Do you feel anxious or frustrated about your diabetes medications?	0.651				0.574
	Q18	Do family gatherings or holidays affect your taking of diabetes medications?	0.635				0.563
	Q25	Do you consider yourself an organized person who is committed to taking your medication?	−0.621				0.43
	Q26	Have you accepted having diabetes and taking diabetes medications?	−0.423				0.811
	Q10	Has taking diabetes medication become a habit for you?	−0.4	0.374			0.587
	Q8	Does reducing the number of pills and dosing times help you adhere to your medication?	0.307				0.869
Perceived Control and Treatment Facilitation	Q7	Do you act as a role model and support others in adhering to their medications?		0.628			0.585
	Q11	Is it easy for you to take your diabetes medication?		0.477			0.721
	Q13	Does your doctor discuss your medications and their side effects with you?		0.461			0.714
	Q9	Do you use any method to organize or schedule your diabetes medications?		0.444			0.819
	Q29	Do you feel satisfied because you have full control over your diabetes?	−0.337	0.416			0.636
	Q22	Do you engage in activities that reduce stress in your life?					0.871
Beliefs about consequences	Q4	Do negative experiences of family members with diabetes affect your adherence to medication?			0.867		0.252
	Q5	Does seeing other patients develop diabetes complications influence you to adhere to your medication?			0.794		0.34
	Q6	Do you believe that understanding the effects of diabetes medications, their side effects, and their interactions with other medications is important?					0.824
Knowledge and Informational Support	Q12	Do you have sufficient knowledge about diabetes and its treatment?				0.777	0.364
	Q14	Does your spouse or immediate family have sufficient knowledge about diabetes and its treatment?				0.583	0.661
	Q16	Do you have sufficient knowledge to manage your diabetes during fasting periods or when engaging in physical exercise?				0.336	0.584

Note: Factor loadings ≥0.40 are shown.

Internal Consistency

Internal consistency reliability of the ASMA domains is summarized in Table 6. Reliability estimates varied across domains. The Psychological and Behavioral Regulation domain demonstrated good internal consistency, with a Cronbach's α of 0.81 and McDonald's ω of 0.83, the Perceived Control and Treatment Facilitation domain showed lower internal consistency (α = 0.56; ω = 0.60), while the Knowledge and Informational Support domain demonstrated questionable reliability (α = 0.61; ω = 0.64). Similarly, the Beliefs about Consequences domain, consisting of two items, showed lower internal consistency (α = 0.56; ω = 0.60). These lower estimates are likely attributable to the small number of items within these domains rather than inadequate item performance.

Construct Validity

Exploratory factor analysis supported a conceptually coherent multidimensional structure of the ASMA questionnaire. The identified domains were theoretically interpretable and aligned with the predefined theoretical framework, primarily the Theoretical Domains Framework (TDF). Each factor represented a distinct yet meaningful construct related to medication adherence, encompassing behavioral regulation, perceived control, knowledge, beliefs about consequences, and psychosocial influences. The separation of domains was conceptually justified, and the content of items within each domain reflected a common underlying construct, supporting the structural coherence of the questionnaire.

Items demonstrated clear alignment with their respective domains, with salient factor loadings and minimal cross-loadings, supporting interpretability of the factor structure. The direction and magnitude of item loadings were consistent with theoretical expectations, including appropriate reverse loadings where applicable. Domains with fewer items remained conceptually interpretable despite lower internal consistency, which is expected in early-stage questionnaire development. Overall, the factor solution showed adequate item–domain correspondence, supporting construct validity based on structural.

Final Factor Structure of the ASMA Questionnaire

The final factor structure of the ASMA questionnaire comprised four retained domains, each representing a distinct and theoretically meaningful aspect of medication adherence. The Psychological and Behavioral Regulation domain included nine items reflecting habit formation, emotional responses, and behavioral control related to medication use. The Perceived Control and Treatment Facilitation domain consisted of five items capturing patients' perceived ease of treatment, organizational strategies, and treatment-related support. The Knowledge and Informational Support domain included three items assessing patients' understanding of diabetes and its management, as well as informational support from close family members. Finally, the Beliefs about Consequences domain comprised two items addressing perceived outcomes of adherence and non-adherence based on observed experiences.

Rationale for the Selected Factor Solution

The selected factor solution was retained based on a combination of statistical adequacy, theoretical interpretability, and alignment with the Theoretical Domains Framework. The final structure demonstrated acceptable model fit, meaningful factor loadings, and clear item–domain alignment, with each domain reflecting a coherent behavioral construct.

Table 6 Internal Consistency Reliability of the ASMA Domains

Domain	Items (Q)	No. of Items	Cronbach's α	McDonald's ω
Psychological and Behavioral Regulation	Q17, Q21, Q28, Q27, Q18, Q25, Q26, Q10, Q8	9	0.806	0.827
Perceived Control and Treatment Facilitation	Q7, Q9, Q11, Q13, Q29	5	0.558	0.601
Knowledge and Informational Support	Q12, Q14, Q16	3	0.610	0.639
Beliefs about consequences	Q4, Q5	2	0.558	0.601

Notes: Internal consistency was assessed only for domains demonstrating unidimensionality. Cronbach's alpha and McDonald's omega were reported where applicable. Single-item domains were not subjected to internal consistency analysis in accordance with COSMIN recommendations.

Alternative factor solutions were examined but were not retained due to reduced interpretability or conceptual overlap. Domains with fewer items were preserved to ensure comprehensive coverage of theoretically important constructs relevant to medication adherence. Overall, the retained factor structure represents a parsimonious and theory-informed model suitable for subsequent validation and application of the ASMA questionnaire. Data are available upon reasonable request from the corresponding author.

Discussion

This study describes the development and initial psychometric evaluation of the ASMA questionnaire, a theory-informed, patient-derived questionnaire designed to assess medication adherence among adults with type 2 diabetes. The findings indicate that medication adherence is shaped by multiple, interacting behavioural and contextual determinants rather than by a single dominant factor. Four domains emerged as clinically meaningful: psychological and behavioural regulation, perceived control and treatment facilitation, knowledge and informational support, and beliefs about consequences. Together, these domains reflect how patients' emotional responses, practical capabilities, informational environments, and experiential beliefs influence long-term engagement with pharmacotherapy.

These findings align with established behavioural perspectives on chronic disease management, while being grounded in patient-reported experiences collected in routine care settings. Importantly, the results reinforce the view that adherence should be understood as a dynamic behaviour embedded within everyday life rather than as a static attribute or binary outcome.[13]

From a population perspective, the determinants identified are likely to be relevant beyond the study sample. Type 2 diabetes is characterised by prolonged treatment trajectories, evolving regimens, and substantial self-management demands. Determinants such as experiential learning from complications, perceived understanding of treatment, emotional burden, and the influence of close family members have been consistently reported across diverse healthcare systems and cultural contexts.[14]

While the relative importance of these determinants may vary across settings, the underlying mechanisms through which they operate—such as habit formation, perceived control, and social support are plausibly shared among adults managing long-term cardiometabolic conditions. Nevertheless, generalisability should be interpreted cautiously, as variations in healthcare access, health literacy, and family involvement may modify how these factors translate into adherence behaviour.[15]

The findings have clear implications for routine clinical practice. They underscore that adherence cannot be adequately assessed or addressed through prescribing decisions or medication counts alone. Instead, brief, structured conversations that explore patients' understanding of their condition, emotional responses to treatment, perceived control, and available social support may provide more actionable insights. At a health-system level, these results support integrating adherence assessment into chronic disease management pathways, particularly in primary care where most patients with type 2 diabetes are followed longitudinally. Such approaches are consistent with person-centred care models and may allow earlier identification of patients who would benefit from tailored education or support before non-adherence manifests as poor clinical outcomes.[16]

Psychological and Behavioral Regulation

This domain captures how psychological states, social contexts, and behavioural patterns interact to influence sustained medication use. The items reflect common real-world challenges, including psychological stress, social pressure, emotional responses to medication, and disruptions to routine during holidays or family gatherings. Together, these findings suggest that non-adherence often arises from cumulative treatment burden rather than deliberate rejection of care. Emotional responses such as anxiety, frustration, boredom, or fatigue are well documented in long-term conditions where treatment benefits are not immediately tangible. Such emotional fatigue has been increasingly recognised as contributing to both intentional and unintentional non-adherence.[17]

These findings are consistent with previous research demonstrating that psychological burden, treatment fatigue, and disruptions in daily routines are important determinants of medication adherence in chronic conditions, including

diabetes and other cardiometabolic diseases. Prior studies have also highlighted the role of stress and emotional responses to treatment as key factors influencing patients' ability to maintain long-term medication routines.

The domain also highlights the importance of habit formation and self-regulation. Difficulties with organisation and routine integration are common and may be exacerbated by complex regimens. Evidence suggests that simpler dosing schedules are more easily incorporated into daily life, supporting sustained adherence. This aligns with previous evidence indicating that regimen simplicity and the ability to integrate medication-taking into daily routines are important facilitators of sustained adherence.[16]

Perceived Control and Treatment Facilitation

This domain reflects how manageable patients perceive their treatment to be within both their personal capabilities and the healthcare environment. Items addressing ease of medication use and organisational strategies highlight the practical dimension of perceived control, which is strongly influenced by regimen complexity and competing life demands.[18] These findings are consistent with previous research showing that perceived treatment burden and regimen complexity are important determinants of medication adherence in chronic disease management.

Clinician–patient communication emerged as a key element of treatment facilitation. Clear discussion of medications and side effects aligns with international evidence showing that bidirectional communication enhances trust, addresses concerns, and supports adherence.[19] Previous studies have similarly demonstrated that effective clinician–patient communication improves patients' understanding of treatment and strengthens adherence behaviour.

Perceived control is not static. Some patients maintain adherence despite low confidence, while others struggle during periods of stress despite high perceived control. The social dimensions, such as acting as a role model, may reinforce adherence for some individuals but are culturally contingent and should not be assumed to operate uniformly.[20] This observation is consistent with evidence suggesting that social and cultural contexts can shape how perceived control translates into medication-taking behaviour.

Knowledge and Informational Support

This domain captures patients' perceived adequacy of knowledge about diabetes and its treatment, extending beyond individual understanding to include family knowledge and situational management skills. Its stability across analytic solutions suggests that knowledge and informational support represent a foundational component of adherence. This finding is consistent with previous research indicating that patients' understanding of their condition and treatment is a key determinant of medication adherence in chronic diseases. Inadequate knowledge is a recognised determinant of suboptimal adherence. However, the findings add nuance by showing that who holds the knowledge and when it is applied are equally important. Family knowledge is particularly relevant in contexts where household members influence daily routines and treatment decisions.[21] Similar observations have been reported in studies highlighting the role of family involvement and shared health knowledge in supporting adherence behaviours.

The ability to manage medications during fasting, exercise, or physiological fluctuations highlights the importance of context-specific skills that are often underemphasised in routine education. These situations are common across populations, yet patients frequently report uncertainty about safe medication use during such periods.[22–24] Previous studies have similarly shown that patients often require practical, situation-specific guidance to manage medications safely during lifestyle changes or physiological stressors.

The persistence of this domain despite high overall adherence suggests that knowledge may function as a maintenance factor rather than merely a barrier, supporting sustained adherence during periods of change or stress. This interpretation aligns with evidence suggesting that knowledge and informational support help sustain long-term adherence rather than solely acting as a corrective factor for poor adherence.

Beliefs About Consequences

This domain reflects how observed or anticipated consequences of diabetes shape medication-taking behaviour. Experiences such as witnessing complications in family members or peers serve as powerful reference points influencing perceived disease

severity and treatment necessity.[24,25] These findings are consistent with previous research showing that patients' beliefs about illness severity and treatment consequences play a central role in shaping medication adherence behaviour.

International evidence indicates that experiential exposure can strengthen adherence-related beliefs even in the absence of personal complications. Prior studies have similarly reported that observing disease outcomes in others can influence perceived vulnerability and reinforce the perceived necessity of treatment.

The cross-domain relevance of these items suggests that beliefs about consequences intersect with motivation, perceived control, and psychological regulation. Importantly, in a sample with generally high adherence, strong consequence-related beliefs may function as protective factors that help sustain adherence rather than as drivers of non-adherence. This interpretation aligns with previous work indicating that perceived consequences may act as motivational drivers supporting sustained engagement with long-term treatment.

From an intervention perspective, this highlights opportunities to reinforce realistic understanding of long-term outcomes through peer narratives or reflective discussion, while avoiding fear-based messaging.

Strengths, Limitations, and Interpretation Boundaries

A key strength of the ASMA questionnaire lies in its patient-derived and theory-informed development process. Unlike many existing adherence tools that focus primarily on medication-taking behaviour, ASMA captures multidimensional determinants including behavioural regulation, perceived control, informational support, and experiential beliefs. The identified domains are clinically interpretable and map onto potentially modifiable targets, enhancing its practical relevance in routine care. Furthermore, the questionnaire demonstrated satisfactory structural validity and internal consistency in initial psychometric evaluation.

It is essential to distinguish between what the data demonstrate and what can be inferred. The study provides evidence of associations between adherence-related domains and self-reported medication-taking behaviour but does not establish causality or temporal ordering. Hypotheses regarding the impact of modifying specific domains require prospective or interventional testingAdditional limitations include the cross-sectional design, reliance on self-report, limited response variability in some items, and evaluation of construct validity primarily through structural evidence. The single cultural and clinical context also limits generalisability, underscoring the need for cross-cultural validation and longitudinal assessment in future research.

Implications for Practice, Policy, and Research

For clinicians, the findings support adopting behaviourally informed approaches to adherence assessment that consider emotional burden, perceived control, knowledge needs, and experiential beliefs. For policymakers and health-system planners, they highlight the limitations of uniform adherence interventions and the value of care models that accommodate behavioural complexity. For researchers, priorities include longitudinal studies, intervention trials targeting specific domains, and cross-cultural validation.

Overall, improving medication adherence in type 2 diabetes should be viewed as a population-level challenge requiring integrated clinical, behavioural, and system-level responses.[25]

Conclusion

The ASMA questionnaire appears to be a promising tool for assessing multidimensional determinants of medication adherence in adults with type 2 diabetes. By capturing behavioural, informational, and experiential factors, it provides a structured framework that may inform more tailored adherence interventions. Its theory-informed and patient-derived development further strengthens its relevance for adherence research and practice. Further validation across diverse populations and settings will be important to confirm its broader applicability and utility.

Data Sharing Statement

Data is available upon reasonable request from the corresponding author.

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